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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/648,676 05/16/96 LEADER

EXAMINER
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AIM1/0331

LINE/ART UNIT	PAPER NUMBER
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1102  
DATE MAILED:

03/31/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- ☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-18 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e):

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 11, 12, 18 are rejected under 35 U.S.C.

§ 102(b) as being anticipated by Betts et al.

Betts discloses a sensing assembly comprising an array of sensors located on one side of a substrate 111. A plurality of conductors are located on the opposite side of the substrate each electrically connected with an electrode of a sensor by a laser induced subminiature hole that is filled with conductive material. An encasement covers the sensor assembly and has at least one channel between inlet and outlet means for allowing flow of analyte and has an opening for exposing the conductors. See col. 2, line 37 to col. 3, line 40; col. 6, line 21 to col. 8, line 46; col. 11, lines 21-53; col. 19, line 29 to col. 22, line 6.

Applicant's claims are considered to be met, because the term "cartridge" in the preamble is not seen to define structural distinction over the Betts device.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section

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102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3, 6, 11, 12 are rejected under 35 U.S.C. § 103 as being unpatentable over Betts et al in view of Schwartz et al.

If "cartridge" is considered to define structural distinction over Betts, applicant's claims differ in that respect.

Schwartz discloses electrochemical sensors in the form of cartridges for placement into a recording instrument to be well-known. See col. 1, line 25.

It would have been obvious for Betts to make his sensor assembly in the form of a cartridge in view of Schwartz, because that form is easy to use. Merely insert the cartridge into a recording instrument and take the reading.

Claims 7-10, 13 are rejected under 35 U.S.C. § 103 as being unpatentable over Betts et al, with or without Schwartz et al.

These claims differ by calling for certain dimensions of the flow channel and the sensor assembly.

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All the recited dimensions are very small and obviously desirable for the Betts sensor assembly, since miniaturization has the advantage of being adaptable for intra vivo use. This is especially true, when Betts himself discloses samples in the microliter range (col. 24, line 35). The exact dimensions are a matter of routine optimizing.

Claims 4, 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Betts et al, with or without Schwartz et al, in view of Grubb.

These claims differ by calling for the internal electrolyte for the reference electrode to be in gel form.

Grubb discloses a gel electrolyte for a reference electrode to be well-known. See col. 2, line 25. It would have been obvious for Betts to adopt a gel electrolyte in view of Grubb, because a gel is immobilized and would prevent sloshing and be position insensitive.

Claims 14, 15 are rejected under 35 U.S.C. § 103 as being unpatentable over Betts, with or without Schwartz et al, in view of Buzza.

These claims differ by calling for the flow channel to have a dome shaped near the oxygen sensor.

Buzza discloses a flow channel having a domed shape near the measuring end 246 of an oxygen sensor 18. See col. 9, line 13.

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It would have been obvious for Betts to enlarge the flow channel near the oxygen sensor, or any sensor, so as to fit its shape.

Claims 16, 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Betts et al, with or without Schwartz et al, in view of Pace and Kuhn et al.

These claims differ by calling for the sensor array to include sensors for measuring sodium, potassium and calcium ions and for hematocrit value.

Pace discloses all these ion sensors to be well-known. See table 1 in column 3. Kuhn discloses a hematocrit sensor to be old. See col. 1, line 6. It would have been obvious for Betts to include these well-known sensors among his array, since the incorporation of conventional features from analogous prior art is within the skill of the art.

Claim 18 is rejected under 35 U.S.C. § 102(b) as being anticipated by Kanno et al or Fogt.

Kanno discloses a flow channel defined by encasement 8 and/or 12. A plurality of ion sensitive electrodes open into the channel. See col. 6, lines 9-61. Fogt shows a similar construction in figure 7. See col. 9, lines 20-45. Applicant's claim does not recite more in terms of structure.

Claims 1-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 7, "subminiature" is vague without quantifying limits.

Claim 2, line 2, should "mount" be --mounted--?

Claims 3, 4, 6, line 1 of each, the words are not properly spaced and are hard to follow.

Claim 6, line 2; claims 7 and 8, line 1; claim 12, line 2; claim 14, line 3 (both occ.), "the flowcell" has no antecedent basis.

Claim 9, line 1, "of composition" should be deleted. Line 2, "and" should be --or--, unless all three are present.

Claim 15, line 1, "a" should be --an--.

Claim 17, line 2, "each" should be cancelled in view of the last word "sensors".

Claim 18, line 5, there should be no space between "non" and "conducting" in view of "nonconducting" at line 2 of the claim. Also, lines 6-10 of the claim do not read correctly. Further, there is no period at the end of the claim.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending SN 08/648,675 and claims 1-60 of copending SN 08/649,009 in view of Betts et al.

All three sets of claims call for the common subject matter of sensor electrodes on one side of a substrate connected to conductors on the opposite side of the substrate by laser induced subminiature holes filled with conductive material. The instant claims further call for an encasement with openings to provide a flow channel for the sample. However, as discussed before, Betts shows such a flow channel structure to be well-known. It would have been obvious to add a flow channel to the inventions described by the claims of '675 and '009.

This is a provisional obviousness-type double patenting rejection.

Applicant should bring to the examiner's attention any copending applications other than SN 08/648,675 and SN 08/649,009 whose subject matter is closely related to these applications. He should also point out and maintain clear lines of distinction among any such applications with these three applications.

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In the specification, page 2, line 23, there is no period at the end of the sentence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ta Tung whose telephone number is (703) 308-3329. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Kathryn Gorgos, can be reached on (703) 308-3328. The fax phone number for this Group is (703) 305-3600.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

7.78  
**Ta Tung**  
**Primary Examiner**  
**Art Unit 1102**

Ta Tung  
March 22, 1997